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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

February 22, 1999

WARNING LETTER
CIN-WL-99-140

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Herbert G. Weiler, Jr.
President
Weiler Welding Inc.
324 E. Second Street
Dayton, OH 45402-1759

Dear Mr. Weiler:

The Food and Drug Administration conducted an inspection of your liquid and gas Oxygen USP transfilling facility January 25-27, 1999. Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (Title 21 Code of Federal Regulations [CFR] Parts 210 and 211). These deviations cause your drug product, Oxygen USP to be adulterated within the meaning of Section 501(a)(2(B) of the Federal Food, Drug and Cosmetic Act (the ACT).

The deviations documented during the inspection included:

A. Failure to maintain complete transfilling and testing records as follows:

   1. Review of the Oxygen From Liquid Transfilling Records showed one occasion in March 1998 and two occasions in April 1998 when the purity assay was blank and the transfilled cylinders were distributed.

   2. The Oxygen From Liquid Transfilling Records use a checkmark for cylinder preparation and both leak tests. They do not list each pre-filled, fill and postfill inspection except for vacuum and heat of compression. The Standard Operating Procedures follow the same format.

B. Failure to analyze the contents of the bulk liquid oxygen storage tank after each liquid oxygen delivery from January 1997 to March 1998. The firm also did not maintain the supplier certificates of analysis for the liquid oxygen deliveries during the same time period and during May, July and October 1998.

C. Weiler Welding has about 300 aluminum cylinders which have been painted green and resemble steel cylinders. The heat sensitive film on the cylinders has been covered and may be subjected to a hammer test during pre-fill inspections.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met.

Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this into account when considering the award of contracts. By copy of this letter, we are advising the Health Care Finance Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care products in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include seizure and injunction.

Please notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed with fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District

cc: Health Care Finance Administration
Chief Carrier Operations Branch
105 West Adams, 15th Floor
Chicago, Illinois 60603-6201